

### **REMARKS**

Claims 1, 3-14 and 18-31 are currently pending in this application. Claims 1, 18, 22, 25-27 and 30-31 have been amended in this Response. Claims 2 and 15-17 were previously cancelled without prejudice to or disclaimer of the subject matter contained therein.

Claim 1 has been amended to recite that ciclesonide and azelastine are “the sole” active ingredients as suggested by the Examiner at the bottom of page 4 of the Official Action. Similarly, claim 18 has been amended to be consistent with claim 1. Support for the amendment to claims 1 and 18 can be found throughout the specification and the claims as originally filed. In particular, Example 1 on page 9 of the instant specification is a pharmaceutical composition comprising ciclesonide and azelastine as “the sole” active ingredients. Therefore, the claim amendments presented herewith have clear specific basis in the specification as filed.

Claims 22, 25-27 and 30-31 have been amended to correct grammatical formalities.

As such, no new matter has been introduced to the claims within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

#### ***I. Rejection of Claims 1, 3-14, 18, 20-23, 25-28 and 30-31 under 35 U.S.C. §103(a)***

The Official Action states that claims 1, 3-14, 18, 20-23, 25-28 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magee et al. (US Application Publication 2002/0111495).

### **RESPONSE**

For the sake of brevity, applicants incorporate herein all arguments made in previous Responses regarding the non-obviousness of the rejected claims over the Magee et al.

reference including all arguments regarding the unexpected superiority of the claimed combination.

Applicants respectfully note the Examiner's comments on page 4 of the Official Action that:

"Regarding the show of unexpected results, the Examiner again refers applicant to the aforementioned argument that while there is a showing of unexpected result, the claims as presently recited do not commensurate in scope. Instead, the Examiner suggests that applicants amend their claims to recite that the "sole" or that the "only two active ingredients" are ciclesonide and azelastine. However, until such amendment is made, the prior art references do indeed render obvious applicant's instant claims." (emphasis added)

Applicants traverse the rejection of these claims. However, solely to advance prosecution, applicants have amended the claims as suggested by the Examiner. In particular, applicants have amended claims 1 and 18 to recite that:

"a.) 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)-phthalazinone (AZELASTINE), or a stereoisomer, a pharmaceutically acceptable salt or physiologically functional derivative thereof, and  
b.) ciclesonide, or a pharmaceutically acceptable salt of ciclesonide, an epimer of ciclesonide, or a physiologically functional derivative of ciclesonide"  
are "the sole" active ingredients contained in the pharmaceutical composition.

Accordingly, because the Examiner has indicated that unexpectedly superior results have been successfully shown by applicants, and because applicants have amended the claims as suggested by the Examiner, the presently pending claims are in condition for

allowance.

As such, the Examiner is respectfully requested to reconsider and withdraw this rejection.

***II. Rejection of Claims 19, 24 and 29 under 35 U.S.C. §103(a)***

The Official Action states that claims 19, 24 and 29 is rejected under 35 U.S.C. 103(a) as being obvious over Magee et al. in view of Calatayud et al. (US Patent No. 5,482,934).

***RESPONSE***

For the sake of brevity, applicants incorporate herein all arguments made in previous Responses regarding the non-obviousness of the rejected claims over the Magee et al. and Calatayud et al. references including all arguments regarding the unexpected superiority of the claimed combination.

Applicants again respectfully note the Examiner's comments on page 4 of the Official Action that:

"Regarding the show of unexpected results, the Examiner again refers applicant to the aforementioned argument that while there is a showing of unexpected result, the claims as presently recited do not commensurate in scope. Instead, the Examiner suggests that applicants amend their claims to recite that the "sole" or that the "only two active ingredients" are ciclesonide and azelastine. However, until such amendment is made, the prior art references do indeed render obvious applicant's instant claims." (emphasis added)

Applicants traverse the rejection of these claims. However, solely to advance prosecution, applicants have amended the claims as suggested by the Examiner. In

particular, applicants have amended claims 1 and 18 to recite that:

“a.) 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)-

phthalazinone (AZELASTINE), or a stereoisomer, a pharmaceutically acceptable salt or physiologically functional derivative thereof, and

b.) ciclesonide, or a pharmaceutically acceptable salt of ciclesonide, an epimer of ciclesonide, or a physiologically functional derivative of ciclesonide”

are **“the sole”** active ingredients contained in the pharmaceutical composition.

Presently rejected claims 19, 24 and 29 depend from claims 1 or 18.

Accordingly, because the Examiner has indicated that unexpectedly superior results have been successfully shown by applicants, and because applicants have amended the claims as suggested by the Examiner, the presently pending claims are in condition for allowance.

As such, the Examiner is respectfully requested to reconsider and withdraw this rejection.

***III. Rejection of Claims 1, 3-14, 18, 20-23, 25-28 and 30-31 under 35 U.S.C. §103(a)***

The Official Action states that claims 1, 3-14, 18, 20-23, 25-28 and 30-31 are rejected under 35 U.S.C. 103(a) as being obvious over Szelenyi et al. (WO01/22955- corresponding to US Patent No. 7,022,687) in view of Schmidt et al. (J. Clin. Pharmacol. 1999, Vol. 39, pp. 1062-1069).

***RESPONSE***

For the sake of brevity, applicants incorporate herein all arguments made in previous Responses regarding the non-obviousness of the rejected claims over the Szelenyi et al.

and Schmidt et al. references including all arguments regarding the unexpected superiority of the claimed combination.

Applicants again respectfully refer to the Examiner's comments on page 4 of the Official Action that:

"Regarding the show of unexpected results, the Examiner again refers applicant to the aforementioned argument that while there is a showing of unexpected result, the claims as presently recited do not commensurate in scope. Instead, the Examiner suggests that applicants amend their claims to recite that the "sole" or that the "only two active ingredients" are ciclesonide and azelastine. However, until such amendment is made, the prior art references do indeed render obvious applicant's instant claims." (emphasis added)

Applicants traverse the rejection of these claims. However, solely to advance prosecution, applicants have amended the claims as suggested by the Examiner. In particular, applicants have amended claims 1 and 18 to recite that:

"a.) 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)-phthalazinone (AZELASTINE), or a stereoisomer, a pharmaceutically acceptable salt or physiologically functional derivative thereof, and  
b.) ciclesonide, or a pharmaceutically acceptable salt of ciclesonide, an epimer of ciclesonide, or a physiologically functional derivative of ciclesonide"  
are "the sole" active ingredients contained in the pharmaceutical composition.

Accordingly, because the Examiner has indicated that unexpectedly superior results have been successfully shown by applicants, and because applicants have amended the claims as suggested by the Examiner, the presently pending claims are in condition for

allowance.

As such, the Examiner is respectfully requested to reconsider and withdraw this rejection.

***IV. Rejection of Claims 19, 24 and 29 under 35 U.S.C. §103(a)***

The Official Action states that claims 19, 24 and 29 are rejected under 35 U.S.C. 103(a) as being obvious over Szelenyi et al. in view of Schmidt et al. and further in view of Calatayud et al.

***RESPONSE***

For the sake of brevity, applicants incorporate herein all arguments made in previous Responses regarding the non-obviousness of the rejected claims over the Szelenyi et al., Schmidt et al. and Calatayud et al. references including all arguments regarding the unexpected superiority of the claimed combination.

Applicants again respectfully refer to the Examiner's comments on page 4 of the Official Action that:

"Regarding the show of unexpected results, the Examiner again refers applicant to the aforementioned argument that while there is a showing of unexpected result, the claims as presently recited do not commensurate in scope. Instead, the Examiner suggests that applicants amend their claims to recite that the "sole" or that the "only two active ingredients" are ciclesonide and azelastine. However, until such amendment is made, the prior art references do indeed render obvious applicant's instant claims."  
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Applicants traverse the rejection of these claims. However, solely to advance prosecution, applicants have amended the claims as suggested by the Examiner. In

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are **“the sole”** active ingredients contained in the pharmaceutical composition.

Presently rejected claims 19, 24 and 29 depend from claims 1 or 18.

Accordingly, because the Examiner has indicated that unexpectedly superior results have been successfully shown by applicants, and because applicants have amended the claims as suggested by the Examiner, the presently pending claims are in condition for allowance.

As such, the Examiner is respectfully requested to reconsider and withdraw this rejection.

**CONCLUSION**

Based upon the remarks, the presently claimed subject matter is believed to be patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the outstanding rejections and allow all pending claims 1, 3-14 and 18-31. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments. The Examiner is specifically authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

**THE NATH LAW GROUP**

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